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EXAMINER

GOTTSCHALK, MARTIN A

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,644

Applicant(s)

FITALL ET AL.

Examiner

Martin A. Gottschalk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/20/2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-38 have been examined.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. In particular, in claim 13 the preamble alludes to further limitation of claim 1, however the claim body stating the limitations has been omitted, thus claim 13 cannot be examined further.

Claim 14 depends from claim 13 and is thus also indefinite. For the purpose of examination, the "prompting" and "receiving" steps of claim 14 will be considered to depend from claim 1 directly without any intermediate limitation.

4. Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. In particular, in claim 31, the preamble alludes to further limitation of claim 21, however the claim body stating the limitations has been omitted, thus claim 31 cannot be examined further.

Claim 32 depends from claim 31 and is thus also indefinite. For the purpose of

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examination, the "prompting" and "receiving" steps of claim 32 will be considered to depend from claim 21 directly without any intermediate limitation.

5. Claims 15, 16, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. As per claims 15 and 16, claim 15 recites, "prompting....of a communication link...", the meaning of which is unclear, thus the claim is indefinite. Claim 16 depends from claim 15 and is therefore indefinite as well. From context and for the purpose of examination, the Examiner will consider the claim to recite "prompting....over a communication link...".

B. As per claim 24, the preamble recites, "The method of claim 5 further comprising...". Claim 5 is a system claim, thus rendering claim 24 indefinite. In comparing the group of system claims depending from claim 1 to the group of method claims depending from claim 21, it appears claim 24 was intended to depend from claim 23 rather than claim 5. For the purpose of examination, the Examiner will consider this to be the case.

Claim Rejections - 35 USC §101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requires of this title.

6. Claims 21-38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, the cited claims fail to apply technology to accomplish the claimed steps of the methods. As claimed, the steps could be performed manually, thus rendering them non-statutory.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

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be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abdoh (US Pat# 6,654,207, hereinafter Abdoh) in view of Knight (PG Pub# US 2002/0099570, hereinafter Knight).

A. As per claim 1 Abdoh discloses a system for data collection, the system comprising:

a database configured for storing data (Abdoh: col 3, lns 1-13; col 3, lns 14-16); and

the data relating to at least two of the following data types:

data from at least one profile subject relating to personal health care for the at least one profile subject (Abdoh: col 2, lns 56-59);

data from at least one health care provider relating to personal health care for the at least one profile subject (Abdoh: col 4, lns 45-53);

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data from the at least one profile subject relating to personal perceptions of interactions by the at least one profile subject with health care providers;

data from the at least one profile subject relating to health care behavior for the at least one profile subject; and

data from at least one third party relating to the health care behavior of the at least one profile subject.

Abdoh fails to explicitly disclose

a server coupled to the database, the server configured for gathering data over one or more communication links.

However, this feature is well known in the art as evidenced by Knight.

Knight discloses a system for recruiting patients for clinical trials, including a database coupled to a secure server for gathering patient data over the Internet (Knight: Figs. 29, items 2902; Fig. 30; [0017]; [0114] – [0122]).

It would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Knight within the system of Abdoh for the purpose of providing a complete computer network system.

The motivation for this combination would have been to rapidly receive and provide more complete and secure information to health care providers and patients regarding treatment options available (Knight: [0004]), thus improving the general satisfaction of the patient (Abdoh: Fig. 1).

B. As per claim 2 Abdoh discloses a system wherein

each of the communication links is selected from the group consisting of
a telephone communication link (Abdoh: col 3, lns 17-18) and
a computer communication link.

C. As per claim 3, Abdoh discloses a system further comprising
an interactive voice response system configured for gathering data from
the at least one profile subjects and providing the responses from the at least
one profile subjects to the server (Abdoh: col 3, lns 14-16).

D. As per claim 4, Abdoh discloses a system wherein the server is further
configured for
storing the gathered data in the database (col 3, lns 40-46).

E. As per claim 5, Abdoh discloses a system wherein the server is further
configured for:
prompting the at least one profile subject over the communication link with
questions (Abdoh: col 3, lns 32-47) directed to the personal health care (Abdoh:
col 2 lns 56-59, reads on "clinical and health outcome") of the at least one profile
subject; and
receiving responses from the at least one profile subject over the
communication link in response to the questions (Abdoh: col 3, lns 39-41).

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F. As per claim 6, Abdoh discloses a system wherein the server is further configured for:

prompting the at least one subject for updated data relating to the personal health care for the at least one profile subject; and

receiving responses from the at least one profile subject over the network communication link in response to the questions.

Claim 6 is rejected for the same reasons given above for claim 5. The Examiner considers the questions and the responses to them referenced in claim 5 to be a form of "updated data".

G. As per claim 7, Abdoh discloses a system wherein the server is further configured for:

prompting at least one health care provider for medical records relating to the at least one profile subject over the communication link; and

receiving data from the at least one health care provider over the communication link (Abdoh: col 4, lns 45-53).

H. As per claim 9, Abdoh discloses a system wherein the server is further configured for:

prompting the at least one profile subject over the communication link with questions directed to the personal perceptions of interactions by the at least one profile subject with health care providers; and

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receiving responses from the at least one profile subject over the communication link in response to the questions (Abdoh: col 2, Ins 59-63).

I. As per claim 10, Abdoh discloses a system wherein

the prompted questions relate to the personal perceptions of the profile subject with respect to the quality of the medical care and the satisfaction of the medical care (Abdoh: col 2, Ins 59-63: Fig. 1).

J. As per claim 11, Abdoh discloses a system wherein

the prompted questions relate to the personal perceptions of the profile subject with respect to the advice, information, and prescribed treatment by one or more health care professionals (Abdoh: col 2, Ins 59-63, reads on "post-visit treatment outcome").

K. As per claim 12, Abdoh discloses a system wherein the server is further configured for:

prompting the at least one subject for updated data relating to the personal perceptions of interactions by the at least one profile subject with health care providers; and

receiving responses from the at least one profile subject over the network communication link in response to the questions.

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Claim 12 is rejected for the same reasons given above for claim 9. The Examiner considers the questions on personal perceptions and the responses to them referenced in claim 9 to be a form of "updated data".

L. As per claim 13, it recites, "The system of claim 1 wherein the server is further configured for: ". See the related rejection above under 35 U.S.C. section 112, paragraph 2.

M. As per claim 14, Abdoh discloses a system wherein the server is further configured for:

prompting the at least one subject for updated data relating to the health care behavior of the at least one profile subject regarding an existing condition; and

receiving responses from the at least one profile subject over the network communication link in response to the questions.

Claim 14 is rejected for the same reasons given above for claim 5. The Examiner considers the questions and the responses to them referenced in claim 5 to be a form of updated data relating to health care behavior (reads on "clinical and health outcome information" in Abdoh: col 2 Ins 56-59).

N. As per claim 15, Abdoh discloses a system wherein the server is further configured for:

prompting at least one third party for records relating to the at least one

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profile subject of a communication link; and

receiving data from the at least one third party over the communication link (Abdoh: col 4, lns 45-53, references a plurality of health care providers, one of which would be considered to be a third party.).

O. As per claim 17, Abdoh fails to disclose a system wherein the server is further configured for:

prompting the at least one potential profile subject with screening questions over the communication link; and

receiving responses from the at least one potential profile subject over the communication link in response to the screening questions.

However, these features are well known in the art as evidenced by the teachings of Knight.

Knight discloses a system that presents and gathers the responses to screening questions from patients who are potential subjects for clinical trials (Knight: [0072]; Figs. 1, 2, and 5).

The motivation to combine the teachings of Knight within the system of Abdoh is the same as provided for in claim 1 and are incorporated herein.

P. As per claim 18, Abdoh fails to disclose a system wherein screening the at least one potential profile subject further comprises the server being configured for:

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comparing the responses from the at least one potential profile subject with candidate population characteristics; and

eliminating a potential profile subject based on the comparison.

However, these features are well-known in the art as evidenced by Knight.

Knight teaches:

comparing the responses from the at least one potential profile subject with candidate population characteristics (Knight: [0058], population

characteristics reads on "...public and private clinical trials in database."; and

eliminating a potential profile subject based on the comparison (Knight: [0058], reads on "...accept only patients that match 100% of the...criteria." Note that patients not making the specified match percentage are eliminated.].

The motivation to combine the teachings of Knight within the system of Abdoh is the same as provided for in claim 1 and are incorporated herein.

Q. As per claim 19, Abdoh fails to disclose a system wherein screening the at least one potential profile subject further comprises the server being configured for:

comparing the responses from the at least one potential profile subject with candidate population characteristics; and

classifying a potential profile subject into one or more studies based on the comparison.

However, these features are well known in the art as evidenced by Knight.

Knight teaches:

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comparing the responses from the at least one potential profile subject with candidate population characteristics; and

classifying a potential profile subject into one or more studies based on the comparison (Knight: [0072]; Fig 2, items 4 and 8; Fig 25A).

The motivation to combine the teachings of Knight within the system of Abdoh is the same as provided for in claim 1 and are incorporated herein.

R. As per claim 20, Abdoh fails to explicitly disclose a system wherein the screening questions further comprise

questions directed to at least one question selected from the group consisting of

- contact details,
- demographics,
- lifestyle,
- past chronic conditions,
- current chronic conditions,
- treatment for current conditions, and
- current medications.

However, this feature is well known in the art as evidenced by Knight.

Knight teaches a system wherein the screening questions further comprise:

questions directed to at least one question regarding

demographics (Knight: Fig 4, reads on "Date of Birth").

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10. Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abdoh in view of Knight as applied to claim 1 above, and further in view of Chilton et al. (Chilton, Lance; Berger, Jan E.; Melinkovich, Paul; Nelson, Richard; et al. "Privacy Protection of Health Information: Patient Rights and Pediatrician Responsibilities." Pediatrics; Oct. 1999; Vol. 104, No. 4; pp. 973-977; hereinafter Chilton.).

A. As per claim 8, Abdoh in view of Knight fails to disclose a system wherein the server is further configured for:

prompting the at least one profile subject with at least one permission form authorizing a health care provider to provide one or more medical records relating to the at least one profile subject over a communication link; and

providing the at least one permission form authorizing the health care provider to provide the one or more medical records relating to the at least one profile subject.

However, these features are well known in the art as evidenced by Chilton.

Chilton discloses the growing use of computerized medical records, and electronic transmission of patient health data; the security risks associated with these methods; and the regulatory constraints being applied to this situation (Chilton: Introductory section and section on "Electronic transmission of Health Data"). Chilton further emphasizes the importance of using signed released

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forms (i.e. permission forms) as security measures (Chilton: section on "Medical Record Release Forms"), and suggests the use of readily available tools such as electronic signatures in maintaining electronic health record security (Chilton: section on "Access to Medical Records", last paragraph.).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the suggestions of Chilton with the combined teachings of Abdoh and Knight in order to enable the legal release of a patient's medical records by a physician electronically. The motivation for this combination would have been to comply with regulatory requirements for security (Chilton: Introductory section, first paragraph), while not unduly burdening the health care provider or impeding the provision of health care (Chilton: Introductory section, third paragraph).

B. As per claim 16, it is rejected for the same reasons provided for claim 8 above, noting additionally that the Examiner considers a "secondary user" to be a third party (Chilton: section on "Primary and Secondary Uses of Health Data").

The motivation to combine the teachings of Abdoh and Knight is the same as given for claim 8 and is incorporated herein.

11. As per claims 21 and 22-38 they are method claims, which repeat the same limitation of claim 1, and 4-20 respectively, the corresponding system claims, as a series of process steps as opposed to a collection of elements. Since the collective teachings of Abdoh in view of Knight (for claims 1, 4-7, and

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9-20), and Abdoh in view of Knight, and further in view of Chilton (for claims 8 and 16) disclose the structural elements that constitute the systems of claims 1, and 4-20, it is respectfully submitted that they perform the underlying process steps, as well. As such, the limitations of claims 21, and 22-38 respectively are rejected for the same reasons given above for claim 1, and 4-20 respectively.

The motivation for incorporating the features of Knight within the system of Abdoh is as given above in the rejection of claim 1, and is incorporated herein.

The motivation for incorporating the features of Chilton within the combined teachings of Knight and Abdoh is as given above in the rejection of claim 8, and is incorporated herein.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not relied upon patent prior art discloses systems and methods for patient evaluation of physician performance (US Pat# 5,924,073 and PG Pub# 2001/003722). The cited but not relied upon non-patent literature discloses the complex nature of consent for disclosure of medical records (Merz).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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